REMARKS

I. Status of the Claims

Claims 1-27 were originally filed. In response to the Restriction Requirement mailed 2006, Applicants elected with traverse Group I, *e.g.* claims 1-5 and 11-18. Claims 6-10 and 19-27 are withdrawn from consideration. Claims 1-5 and 11-18 are currently pending.

II. Rejections Under 35 U.S.C. § 112, First Paragraph

The Action rejects claims 1-4, 11, and 13-18 as not enabled for transformation of any type of plant. Applicants respectfully traverse.

The Action fails to make a prima *facie case* of non-enablement. In particular, the action relies solely on the uncertainty of plant cell transformation using *Agrobacterium*. For example, the Action cites Zhao *et al.*, 2001 at page 323, second column, second paragraph to page 324, first column, first paragraph as teaching that:

> Various factors have been shown to affect plant transformation efficiency when *Agrobacterium* is used to deliver T-DNA into plant cells. Those factors include explant type and age, *Agrobacterium* strains and type of binary vectors, medium and co-cultivation conditions, etc. (citations omitted)

However, the present claims are not limited to *Agrobacterium*-mediated transformation and are directed to "transformation of the haploid sporophytic tissue" generally. The present specification states in paragraph [0080]:

> The technologies for the introduction of DNA into cells are well known to those of skill in the art and can be divided into categories including but not limited to: (1) chemical methods; (2) physical methods such as microinjection, electroporation, and the gene gun; (3) viral vectors;(4) receptor-mediated mechanisms; and (5) Agrobacterium-mediated plant transformation methods.

Second, the Action fails to take Zhao *et al.* as a whole. Contrary to the interpretation of Zhao *et al.* provided in the Action, Zhao *et al.* taken as a whole supports the enablement of *Agrobacterium*-mediated transformation. For example, Zhao *et al.* teach that *Agrobacterium*-mediated transformation has been successful in a wide range of monocotyledonous plants such as rice, maize, wheat, barley and sorghum. Zhao *et al.*, page 323, first paragraph of the introduction states:

> Because monocotyledonous plants, such as maize, are rarely natural hosts for *Agrobacterium*, they were not expected to be susceptible to genetic transfer mediated by *Agrobacterium* []. However, subsequent studies showed that *Agrobacterium*-mediated DNA transfer to maize was very efficient []. Recently, transgenic plants and progeny from important monocotyledonous crops, such as rice [], maize [], wheat [], barley [] and sorghum[] have been obtained using *Agrobacterium*. (citations omitted)

In addition, while multiple factors may be required in the success of such protocols, the reference readily illustrates that these factors and their optimization was well known in the art. Thus, the allegation that Zhao *et al.* indicates the unpredictability of *Agrobacterium* mediated transformation is not supported by the Zhao *et al.* reference.

Furthermore, the Action alleges that Hansen *et al.* teach that plant transformation is "not an exact science, but more of an art because of the unique culture conditions required for each crop species and that to accommodate a species that has not been manipulated in culture previously one must either adapt an established protocol or create a new on, bearing in mind the efficiency imperatives." Action page 4 citing page 230, second column, first paragraph of Hansen *et al.* (1999). However, Hansen *et al.* taken as a whole describe advances in transformation technology and also fails to suggest that the claims are not enabled. In particular, Hansen *et al.* discuss those particular advances made in the transformation of previously recalcitrant species. Hansen *et al.*, on page 226, right column first paragraph state: "In recent years, many crops, previously classified as recalcitrant because they were stubbornly resistant to

the overtures of genetic engineering, have now been transformed." Applicants have found no teaching in Hansen *et al.* that would indicate that transformation in general is an unpredictable art. A method need not be an exact science to teach one of skill how to make and use the invention.

The test of enablement is whether the specification teaches a person of ordinary skill in the art how to make or use the invention without undue experimentation. MPEP § 2164.01. Whether making and using a claimed invention requires undue experimentation is not a single factual determination, but rather, it is a conclusion reached by weighing all of the Wands factors. MPEP §2164.01(a) (citing *In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988)). It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the Wands factors while ignoring others. *Id.* Appellants respectfully submit that the Specification contains sufficient direction to allow one of skill in the art to practice the invention without undue experimentation.

In view of the foregoing, Applicants respectfully request the withdrawal of the enablement rejection.

III. Rejections Under 35 U.S.C. § 103

A. Claims 1-5 and 11-18 Are Rejected Based on 35 U.S.C. § 103 Over U.S. Publication 2002/0188965 in Light of U.S. Patent 5,770,788

The Action rejects claims 1-5 and 11-18 as unpatentable based on U.S. Publication 2002/0188965 ('965 publication) in light of U.S. Patent 5,770,788 ('788 patent). In particular, the Action alleges that the '965 publication describes producing a dihaploid tissue from a haploid tissue and that it would have been obvious to one of skill to use colchicine as described in the '788 patent to obtain the claimed methods of obtaining dihaploid sporophytic tissues. Applicants respectfully traverse.

One of skill in the art would not be motivated to combine the '788 patent, which is directed specifically to microspore culture and treatment with colchicine, with the description of the '965 publication that is directed to haploid somatic cells, a cell type that is distinct from the microspores described in the '788 patent. For example, the '788 patent states in column 2 line 10 to line 15:

> According to the present invention there is provided a method for the production of plants, comprising ***culturing anthers or pollen*** of the target plant in a culture medium containing an effective amount of a chemical agent capable of inducing chromosome multiplication in haploid cells. (emphasis added)

Similarly, column 2, line 29 to line 34 states that:

> Thus, our invention is based on our discovery that *there is a particular stage in microspore-derived embryo development* . . . during which chemical agents capable of inducing chromosome multiplication is most effective. (emphasis added)

This distinction is also provided by the '694 patent that states in column 2 line 49 to line 55:

> We surprisingly found that ***microspore transformation*** via *A. tumefaciens* is practicable and leads to fertile homozygous plants with predominantly single copy inserts . . . Thus fertile homozygous plants with single copy inserts can be produced in only one generation using embryogenic microspores and *A. tumefaciens*. (emphasis added)

Therefore, one of skill in the art would have been taught that colchicine treatment was effective in treating and inducing chromosome multiplication in haploid microspore tissue under conditions specific for microspore tissue. Thus, one of skill would not be motivated to combine the cited references and would not have a reasonable expectation that haploid somatic cells could be successfully processed using techniques developed for microspores.

Applicants respectfully request the withdrawal of the rejection.

B. Claims 1-5 and 11-18 Are Rejected Based on 35 U.S.C § 103 Over U.S. Patent 6,316,694

The Action rejects claims 1-5 and 11-18 as being unpatentable over U.S. Patent 6,316,694 ('694 patent). In particular, the Action alleges that the '694 patent obviates the currently claimed subject matter because the '694 patent teaches:

> . . . a method of obtaining a transformed dihaploid plant comprising obtaining *embryogenic microspores and transforming embryogenic microspores* wherein the transformed embryonic microspores are capable of leading to a transformed haploid or doubled haploid embryo that develops into a fertile homozygous plant. (emphasis added)

The Action reasons that, although the '694 patent does not teach a haploid sporophytic tissue, this is suggested by the statement "Microspore culture can induce an alternative (sporophytic) pathway which leads to the formation of haploid and doubled haploid embryos." Applicants traverse as: (1) the '694 patent does not teach all presently claimed elements, particularly the *transformation* of a haploid sporophytic tissue and the production of a dihaploid tissue from *a transformed sporophytic tissue*; and (2) one of skill in the art reading the '694 patent would not have a reasonable expectation that transformation of a haploid sporophytic tissue would be obtainable, much less successful. In support, Applicants note that the word "sporophytic" is used once in introduction of the '694 patent to describe the process of inducing a microspore culture to develop a haploid or dihaploid embryo. The word "sporophytic" is not used in the context of transformation or the production of a transformed plant. In fact, the '694 patent teaches away from the transformation of a haploid sporophytic tissue by strictly limiting the methods to embryonic microspores. For example, the '694 patent in column 2 lines 53 to 55 states: "Thus fertile homozygous plants with single copy inserts *can be produced in only one generation using embryogenic microspores and A. tumefaciens*." (emphasis added) Thus, the

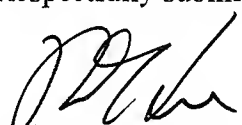
'694 patent not only fails to teach all elements of the claimed invention, but also fails to provide a reasonable expectation of success as viewed by one of skill in the art.

Applicants therefore respectfully request the withdrawal of the obviousness rejections under 35 U.S.C. § 103.

CONCLUSION

Applicants believe that the present document is a full response to the Action dated May 4, 2006. The Examiner is invited to contact the undersigned Attorney at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Robert E. Hanson
Reg. No. 42,628
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Ave., Suite 2400
Austin, Texas 78701
(512) 536-3167
(512) 536-4598 (facsimile)

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